UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 16-2738 (FLW-LHG)**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE GEOLOGIC TESTING OPINIONS OF DRS. ANN G. WYLIE AND MELINDA DARBY DYAR

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

I. INTRODUCTION

The Plaintiffs' Steering Committee ("PSC") respectfully submits this motion, pursuant to Fed. R. Evid. 104 (a), 702, 703 and 403, to exclude the opinions and testimony of Defendants' geologic testing experts, Ann G. Wylie, Ph.D. and Melinda Darby Dyar, Ph.D. Both experts were tasked with critiquing the testing methodology and conclusions of Plaintiffs' experts, Drs. William E. Longo and Mark W. Rigler.[1] Dr. Dyar, for example, testified that "[she] was asked to review the methodology used by Drs. Longo and Rigler in a series of reports… and to write a report giving my review."[2] As outlined below, neither Dr. Wylie nor Dr. Dyar are qualified to opine on the testing done by Drs. Longo and Rigler. Further, to the extent Defendants' experts opine on the testing, their methodology falls well short of the standards articulated by the United States Supreme Court in *Daubert v.*

[1] Unless otherwise stated, references to Dr. Longo or Dr. Rigler are meant to include reference to the team of analysts who worked collectively in analyzing talcum powder samples.

[2] *See* April 2, 2019 Deposition of Melinda Darby Dyar, Ph.D. ("Dyar Dep.") at 16:17-22, attached hereto as Exhibit A. Dr. Wylie testified similarly, stating that the scope of work was to "review the literature on the deposits that had been used by Johnson & Johnson, Italy and Vermont, and that I would review the reports that were provided by Drs. Longo and Rigler." *See* March 13, 2019 Deposition of Ann G. Wylie, Ph.D. ("Wylie Dep.) at 13:18-22, attached hereto as Exhibit B. *See also* Wylie Dep. at 58:9-12 ("My charge was to review the literature and the reports of Drs. Longo and Rigler. So it did not include requests to review anything else.").

Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). Their opinions, therefore, should be excluded.

II. FACTUAL BACKGROUND

A. Plaintiffs' Steering Committee Experts Dr. William E. Longo and Dr. Mark W. Rigler

Dr. William E. Longo has a Bachelor of Science degree in Microbiology, a Master of Science degree in Engineering and a Doctorate in Philosophy in Materials Science, from the University of Florida.[3] Dr. Longo is a member of numerous organizations and professional groups specializing in the testing and analysis of asbestos-containing materials, including the Environmental Protection Agency (EPA) Peer Review Group for the Asbestos Engineering Program, the American Industrial Hygiene Association (AIHA), Materials Research Society, American Society for the Testing of Materials (ASTM), and the American Society of Materials.[4]

Dr. Longo has been analyzing products and other samples for whether they contain asbestos for over 30 years.[5] Under his direction, his laboratory has tested

[3] *See Curriculum Vitae* of William E. Longo, Ph.D. attached as Exhibit C.

[4] *See* June 30, 2011 Affidavit of William E. Longo, Ph.D. ("Longo Aff.") at ¶ 9, attached hereto as Exhibit D.

[5] *See* February 5, 2019 Deposition of William E. Longo, Ph.D. ("Longo Dep.") at 350:11-15, attached hereto as Exhibit E.

between 300,000 and 400,000 individual samples of asbestos products.[6] Dr. Longo's employer, MAS, LLC is a leading engineering consulting firm, which provides a broad range of services including environmental and industrial hygiene and emissions testing.[7]

Dr. Rigler, also an employee of MAS, has been analyzing products and other samples for whether they contain asbestos for over 25 years.[8] Dr. Rigler has a Bachelor of Science degree in biology from Villanova University.[9] He also holds a Ph.D. in microbiology from the University of Georgia with a heavy emphasis on using electron microscopy techniques.[10] Dr. Rigler has designed custom analytical protocols for product and chemical studies and has extensive laboratory management experience.[11] Dr. Rigler helped develop the quality control program at MAS which requires certification by the National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program ("NIST NVLAP").[12] Dr. Rigler is responsible for ensuring that the studies conducted at

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[6] *Id.* at 348:23-349:4.

[7] Longo Aff. at ¶ 12.

[8] *See* February 6, 2019 Deposition of Mark W. Rigler, Ph.D. ("Rigler Dep."), at 220:20-223:2, attached hereto as Exhibit F.

[9] *Id. at* 219:21-220:3.

[10] *Id*. at 220:4-8.

[11] *Id.* at 224:3-225-4.

[12] *Id.* at 224:3-225-4.

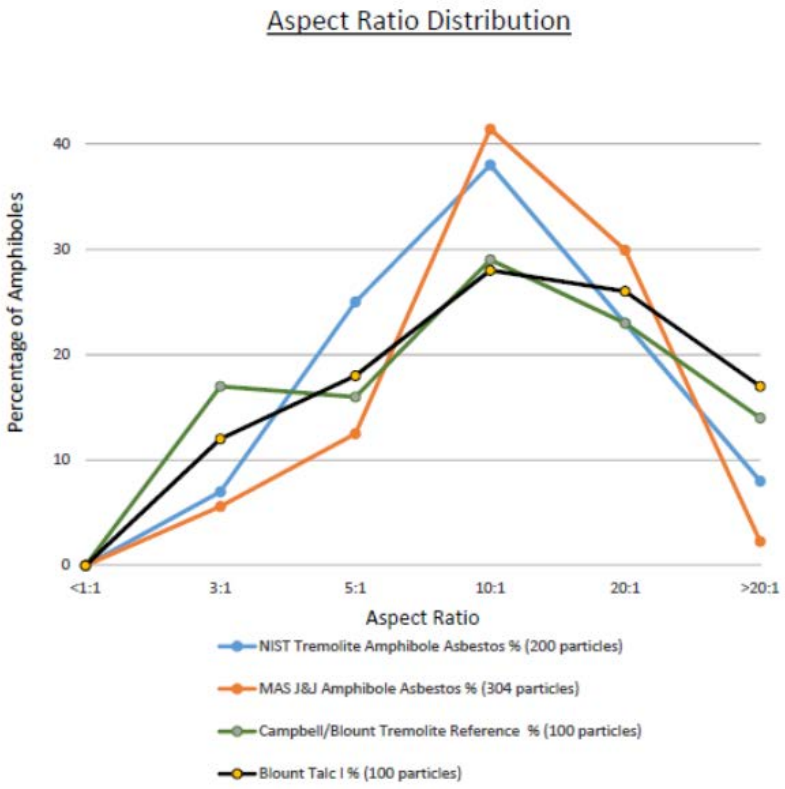
MAS follow the quality protocols and standards required by various lab certification bodies.[13]

To perform its work, MAS has employees with expert knowledge of a broad range of fields including materials sciences, chemistry, physics, biology, industrial hygiene, geology, mechanical engineering, and microscopy. MAS utilizes multiple, standardized analytical techniques. The MAS methods include the very testing techniques routinely employed by and available to industry in the 1960s and 70s, as well as updated, standardized testing procedures.[14] For example, the aspect-ratio distribution for the asbestos fibers identified by Dr. Longo in his testing are virtually identical to a number of other analyses on undisputed asbestos samples, including those conducted by Dr. Alice Blount, a former consultant to Johnson & Johnson, the National Institute of Standards Technology (NIST), and the United States Geological Survey (USGS).

[Image Below]

[13] *Id.* at 225:10-227:13.

[14] Longo Aff. at ¶ 12.



The EPA requested that Dr. Longo, and other scientists, help develop the EPA's protocol for taking and analyzing settled asbestos dust samples.[15] As a member of ASTM, Dr. Longo was responsible for writing the ASTM asbestos dust analysis standards.[16] In addition, Dr. Longo has published numerous articles on the subject of the analysis and testing of asbestos-containing materials. Dr. Longo regularly performs work for clients not involved in litigation. In all of his work, regardless of whether performed on behalf of plaintiffs or defendants in litigation, performed for matters not involving litigation, or performed for this litigation, he

[15] Longo Aff. at ¶ 10.

[16] *Id.*

utilizes the same generally accepted methodologies and analysis for testing.[17] MAS videotape demonstrations and studies are used for educational and training purposes in conjunction with the American Industrial Hygiene Association, American Society of Safety Engineers, the Environmental Institute, AHERA certification training, and the U.S. Public Health Service.[18]

Dr. Longo was tasked with analyzing samples of Defendants' talcum powder products for the presence of asbestos and fibrous talc. He did so using the generally accepted methodologies regularly employed in his lab, including transmission electron microscopy (TEM) which is widely recognized as the only analytical method and tool with the appropriate sensitivity for analysis of asbestos contamination at low levels (by weight) typically seen in talc.[19] Using TEM analysis, each talcum powder sample was tested for the presence of asbestos using information obtained from the electron microscope about the particles' chemical signature (determined using EDS/EDXA analysis), its' crystalline structure (determined by SAED analysis), and by measuring overall size and shape using photomicrographs (morphology and aspect ratio). In addition to using TEM, Dr.

[17] *Id*. at ¶ 14.

[18] *Id*.

[19] Since at least the 1970s, Defendants have acknowledged that "there seems to be general agreement that Transmission Electron Microscopy is the only absolute proof with electron diffraction for the identification of asbestos in talc." *See* January 3, 1974 Johnson & Johnson memo from A. J. Goudie, attached hereto as Exhibit G.

Longo and his lab also analyzed many of the samples using a polarized light microscope (PLM)[20] and x-ray diffraction (XRD), none of which are as sensitive as TEM for the detection of asbestos, but which provide additional confirmatory information about the presence of asbestos in talcum powder samples.

B. Summary of the Opinions of Ann G. Wylie, Ph.D.

Dr. Wylie was a professor of geology at the University of Maryland until her retirement in 2014, and she continues to hold an appointment as Professor Emerita.[21] During her career Dr. Wylie has published articles on talc, amphibole and asbestos, including papers related to asbestos in ambient air and water.[22] However, Dr. Wylie has no experience in the use of TEM to test for the presence of asbestos.[23] Dr. Wylie opines that it is "highly unlikely" that asbestos could be found in Defendants' talcum powder products due to the geologic settings, reports from the mine geologist, and literature descriptions of the ore deposits she reviewed.[24] Her opinions rely upon a definition of talc as a mineral formed by the alteration of Mg-rich rocks,[25] and a definition of amphibole and serpentine minerals as common rock-forming minerals

[20] Polarized light microscopy was also used to analyze the samples for fibrous talc.
[21] *See* February 25, 2019 Expert Report of Ann G. Wylie, PhD For General Causation *Daubert* Hearing ("Wylie Report") at 2, attached hereto as Exhibit H.
[22] *Id.* at 3.
[23] *See* Wylie Dep. at 227:7-16.
[24] Wylie Report at 18.
[25] Wylie Report at 3.

that can be associated with talc ore but that "occur rarely as asbestos."[26] She asserts that "mineral fiber is uncommon," and that amphiboles that form in the asbestiform habit "exhibit special properties that are different than those same amphiboles that otherwise form in nature."[27] Dr. Wylie states that cleavage fragments[28] are not asbestos or asbestiform and "do not have the properties of asbestos."[29] She opines that regulatory standards are overly broad and "obscure the fundamental characteristics of asbestos," thereby creating false positives in testing for asbestos.[30] She states that the formation of talc "does not require or favor the formation of asbestos in the ore,"[31] and that OSHA's "oversimplified" regulations "confused the distinctions between asbestos and cleavage fragments."[32]

With respect to the work done by Drs. Longo and Rigler in this litigation and the opinions they have offered, Dr. Wylie opines that their reports "do not present evidence consistent with the optical properties or habit of asbestos."[33] Her opinions

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[26] Wylie Report at 4.

[27] Wylie Report at 6.

[28] According to Dr. Longo, particles which have less than a 3 to 1 ratio are cleavage fragments. *See* Longo Dep. at 173:23-174:1.

[29] Wylie Report at 9.

[30] Wylie Report at 11.

[31] Wylie Report at 22.

[32] Wylie Report at 22.

[33] Wylie Report at 13.

in regard to Drs. Longo and Rigler are based upon her position that polarized light microscopy ("PLM") is effective for detecting and identifying the particular "optical properties" that are characteristic of cleavage fragments.[34] She opines that PLM is a more reliable instrument than the TEM employed by Drs. Longo and Rigler and that TEM does not distinguish between elongated mineral particles ("EMPs") of talc and anthophyllite, a type of amphibole asbestos.[35] In Dr. Wylie's opinion, the photomicrographs in the reports of Drs. Longo and Rigler document cleavage fragments, not asbestos, because "they are not bundles,"[36] one "cannot simply calculate [the] aspect ratio" to determine if a particle is asbestiform.[37]

C. <u>Summary of Dr. Dyar's Opinions</u>

Dr. Dyar is the current chair of the Department of Astronomy at Mount Holyoke College. She studied geology at Wellesley College and has a PhD in geochemistry and mineralogy from MIT.[38] She has taught general mineralogy and authored basic mineralogy textbooks but, despite being well published, Dr. Dyar has

[34] Wylie Report at 13.

[35] Wylie Report at 17.

[36] Wylie Report at 15.

[37] Wylie Report at 17.

[38] *See* February 25, 2019 Expert Report of M. Darby Dyar, PhD for General Causation *Daubert* Hearing ("Dyar Report") at 5, attached hereto as Exhibit I.

little to no experience with asbestos, in general, or protocols for testing for the presence of asbestos in bulk materials.

Dr. Dyar's opinions focus on the opinions and analysis of Drs. Longo and Rigler and the testing performed by both. She opines that the work done by Drs. Longo and Rigler was inherently designed to achieve the results they desired for purposes of this litigation and that no asbestos minerals are present in the material Drs. Longo and Rigler tested. However, Dr. Dyar does no independent testing or analysis to contradict the findings of Plaintiffs' experts. She offers no opinions relating to her testing or analysis, labeling her subjective beliefs as opinions founded in expert judgment.

Despite her criticisms, Dr. Dyar is unable to walk away from the fact that Drs. Longo and Rigler and their team of analysts used proper analytical tools – three different analyses using TEM in addition to PLM – to analyze the talcum powder samples that were tested. Nor can Dr. Dyar deny that they used generally accepted ISO standards for testing asbestos in bulk samples, generally, and for asbestos and fibrous talc in talcum powder, specifically, something that she had not previously done herself or even seen prior to being engaged by Defendants as an expert.

III. LEGAL STANDARDS

The PSC incorporates as if set forth in entirety the legal standards set forth in *The Plaintiffs' Steering Committee's Omnibus Memorandum of Law Regarding*

Daubert Legal Standard and Scientific Principles for Assessing General Causation ("Omnibus brief") as supplemented herein.

IV. ARGUMENT

A. Drs. Wylie And Dyar Lack the Experience and Qualifications Necessary to Opine on the Validity of TEM Testing and the Findings of Drs. Longo and Rigler

As the parties offering Drs. Wylie and Dyar, the burden is on Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. (hereinafter "J&J") to demonstrate that the experts are qualified and have used a reliable scientific method to reach their opinions. *See Padillas v. Stark-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999). It is well-settled that "[a]n expert witness must have such skill, knowledge, or experience in the field as to make it appear that his opinion will probably aid the trier of fact in his search for the truth." *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir. 1987).

While courts have recognized a "liberal standard" for qualifying experts, the Third Circuit has made it clear that there is "a floor with respect to an expert witness's qualifications." *Elcock v. Kmart Corp.*, 233 F.3d 734, 743 (3d Cir. 2000). This Circuit has "not pursued a policy of qualifying any proffered witness as an expert." *Id.* (quoting *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998). A court still must focus on whether the qualifications that an expert does have provide a foundation for the witness to testify meaningfully on a given matter. *See Buzzerd v.*

Flagship Carwash of Port St. Lucie, Inc., 669 F. Supp. 2d 514, 522 (M.D. Pa. 2009) (citing *Rose v. Truck Centers, Inc.*, 611 F. Supp. 2d 745, 749 (N.D. Ohio 2009) ("The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.")). A basic understanding of a general subject matter does not alone qualify a witness as an expert on that specific subject. *See In re Unisys Sav. Plan Litig.*, 173 F.3d 145, 156-57 (3d Cir. 1999). Even when a witness is qualified as an expert in a particular field, the court cannot permit the witness to testify as to matters that are outside the area of his expertise. This prohibition applies even when the subject matter of the testimony is related to the witness' area of expertise. *See D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, 03-cv-1026 (MLC), 2006 WL 755984, at *3 (D.N.J. Mar. 20, 2006) ("If an expert's area of expertise is adjacent to, but not actually encompassing, the subject matter of his testimony, he may be deemed unqualified.").[39] Any testimony outside the expert's area of expertise must be stricken. *See Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1180 (3d Cir. 1976) (excluding testimony as to whether a landslide

[39] *See also Player v. Motiva Enterprises LLC*, 02-cv-3216 (RBK), 2006 WL 166452, at *5 (D.N.J. Jan. 20, 2006) (finding that an expert who was experienced in appraising uncontaminated properties was unqualified to provide an opinion on the value of contaminated properties).

was caused by an earthquake because, although expert was a geologist, he had no training in seismology).

1. Dr. Wylie Lacks the Necessary Qualifications to Opine on TEM Testing and the Findings of Drs. Longo and Rigler

Dr. Wylie is not qualified to opine on the use and results of the TEM testing performed by Drs. Longo and Rigler. Dr. Wylie has admitted that she has never used TEM to test for the presence of asbestos.[40] She further testified that if asked to use TEM to evaluate for asbestos she would not be able to make determinations and her opinions would be nothing more than a guess.[41] When analyzing a sample with TEM, Dr. Wylie is unable to make distinctions with a reasonable degree of scientific certainty as to whether the particle she is viewing is asbestos, and therefore, she does not possess the necessary qualifications and expertise to criticize Drs. Longo and Rigler's TEM analysis of talcum powder samples.[42] Admittedly, when it comes to looking at particles under TEM, Dr. Wylie is "not at all clear what's going on."[43] As a result of Dr. Wylie's lack of knowledge and qualifications specific to TEM she should be precluded from commenting on TEM or the use of TEM by Drs. Longo and Rigler.

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[40] Wylie Dep. at 227:7-16.

[41] *Id*. at 209:8 – 210:19.

[42] *See* Wylie Dep. at 211:24-213:2.

[43] *Id.* at 215:17-216:3.

2. Dr. Dyar Lacks the Necessary Qualifications to Opine on the Findings of Drs. Longo and Rigler Related to Asbestos or the Presence of Asbestos in Defendants' Talcum Powder

Dr. Dyar is not qualified to opine on appropriate methods for testing for asbestos. She has almost no personal or relevant experience testing for asbestos. She has neither written about nor tested a sample of talc or talcum powder to determine whether or not it contained asbestos.[44] She spends "zero" time on a daily, weekly or yearly basis analyzing material to determine whether or not they contain asbestos.[45] In fact, Dr. Dyar has **never** analyzed any sample, whether talcum powder or not, to determine if it contained asbestos.[46] She admitted that, despite spending nearly 3,000 hours a year in a laboratory, less than 10 of those hours are spent analyzing samples which may include asbestos that had already been identified.[47]

Most of Dr. Dyar's "knowledge" was acquired specifically for litigation. Prior to being retained, she had never looked at any of the asbestos testing protocols that are essential to Dr. Longo's testing and this case, including the ISO protocols, the Yamate publication from the U.S. Environmental Protection Agency or the

[44] Dyar Dep. at 50:1-4; 58:10-17.

[45] *Id.* at 54: 3-14.

[46] *Id.* 58:10-17; 297:7-19

[47] *Id.* at 364:22-365:7.

Blount paper.[48], [49] Not only has she "never devised a protocol for analyzing asbestos in anything,"[50] she has never relied on any "published protocol for analyzing the presence of asbestos."[51] Dr. Dyar first reviewed the Blount preparation method after she was retained for purposes of this litigation,[52] but she did not read Alice Blount's deposition related to the preparation method or any correspondence between Dr. Blount and J&J regarding asbestos in talcum powder.[53] Dr. Dyar could not say whether ISO 22262-2, an air quality testing standard, is a reliable method to analyze whether or not there are small amounts of asbestos in talcum powder. In fact, she stated that she did not know what the International Standard Organization is.[54]

In her report, Dr. Dyar is very critical of Dr. Longo's identification of asbestos fibers and bundles. However, her knowledge on asbestos bundles appears to have

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[48] Blount, A M. "Amphibole Content of Cosmetic and Pharmaceutical Talcs." *Environmental Health Perspectives* 94 (August 1991): 225–30, attached as Exhibit J. Dr. Blount analyzed samples from talc mines, including Vermont mines that were used to source Johnson & Johnson's talcum powder, and found that certain of those samples were positive for asbestos.

[49] Dyar Dep. at 62:22- 63:14; 63:18-21; 67:5-12; 67:16-68:22.

[50] *Id.* at 264:22-265:5.

[51] *Id.* at 265:6-18.

[52] *Id.* at 101:2-10.

[53] *Id. at* 102:25-103:10.

[54] *Id.* at 61:19-21.

been acquired during her research for her report, as she noted that bundle is not a term she generally uses to describe minerals.[55] Dr. Dyar admitted that she has "very little experience looking at amphibole bundles in thin section, which is why [she] referred to the literature to find what those images looked like."[56] When asked about the relevant forms of asbestos and bundles she had no independent professional knowledge. Instead, she presumed that tremolite can form as an asbestiform bundle based on the image she found for her report purporting to show a tremolite bundle.[57] (She was unaware if anthophyllite could form as an asbestiform bundle.[58]

Dr. Dyar has never published anything in a peer-reviewed journal about testing talcum powder to determine if it contains asbestos.[59] In fact, she has never published a peer reviewed article regarding how to determine if there is asbestos in any product.[60] Additionally, she has never published on how to use EDS, SAED or PLM testing methods to identify asbestos in materials.[61] The only papers that she has contributed to regarding asbestos involved testing for vermiculite in Libby,

[55] *Id.* at 184:11-18.

[56] *Id.* at 293:21-294:17.

[57] *Id.* at 184:11-185:9.

[58] *Id.* at 185:10-15.

[59] *Id.* at 50:5-9.

[60] *Id.* at 46:24-47:2.

[61] *Id.* at 47:3-19.

Montana. However, her contribution to that paper had nothing to do with asbestos but was limited to an analysis of the iron redux ratio.[62]

Dr. Dyar is also not qualified to opine on the presence or absence of asbestos in mines where Defendants' talcum powder was derived. Dr. Dyar has no knowledge regarding talc mines and their geology and accessory minerals. She had "no idea" what accessory minerals were found in talc ore from the Vermont mines from which Defendants obtained talc.[63] When asked if talc deposits can have differing amounts of accessory minerals in the ore she stated "I know nothing about talc mines, so I can't answer any questions relating to talc occurrences in mines."[64] In fact, Dr. Dyar acknowledged that she has no opinion whether talcum powder can be contaminated with asbestos.[65]

Based upon the absolute lack of experience and qualifications related to TEM, the opinions of Drs. Dyar and Wylie regarding TEM testing methods and specifically, the criticisms of Drs Longo & Rigler's methodology and results derived

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[62] *Id.* at 58:18 – 60:16.

[63] *Id.* 96:18-24.

[64] *Id.* at 164:5-16. In fact, Dr. Dyar testified that "I honestly don't know anything about talc mines. I do know that rocks that contain talc can have a wide variety of mineral assemblages, but I don't know anything about mines specifically." *Id.* at 163:18-164:3.

[65] *See id.* at 97:13-18. *See also id.* at 114:15-115:9 ("…and I have not researched [whether talc can be contaminated with anthophyllite asbestos or tremolite asbestos] personally, so I have no opinion on it.").

from TEM testing, should be excluded. Further, the Court should exclude in total the opinions of Dr. Dyar regarding the presence or absence of asbestos in Defendants' products because, admittedly, she knows nothing about the methods used to test for the presence of asbestos in talcum powder and knows nothing about talc mines or the minerals that may be present in those mines.

B. The Methodologies Employed by Drs. Wylie and Dyar Render Their Opinions Unreliable

The decision to admit or exclude an expert's opinion depends upon "whether the 'particular opinion is based on valid reasoning and reliable methodology.'" *Oddi v. Ford Motor Co.*, 234 F.3d 145i146 (3d Cir. 2000) (citation omitted). Focusing on extremely limited evidence or ignoring the totality of available relevant scientific proof renders an expert opinion unreliable and scientifically unsound. *In re Neurontin Mktg. & Sales Practices Litig.*, 04-cv-10739, 2011 WL 3852254, at *34 (D. Mass. Aug. 31, 2011), *aff'd*, 712 F.3d 21 (1st Cir. 2013) (excluding expert's testimony where it was found that the expert "reach[ed] his opinion by first identifying his conclusion… and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of evidence that contradicts his conclusion."). "An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively chooses his support from the scientific landscape.'" *In re Zoloft (Setraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 449 (E.D. Pa. 2014) (finding expert's opinion not reliable or

scientifically unsound because the expert failed to account adequately for contrary evidence). "The reliability of an expert's opinion should be seriously questioned when it is shown that the expert formed his or her opinion prior to reviewing scientific evidence, and, thereafter, merely cherry-picked evidence favorable to that opinion." *In re Seroquel Prods. Liab. Litig.*, 06-md-1769, 2009 WL 3806434, at *5 (M.D. Fla. June 18, 2009).

The opinions of Drs. Wylie and Dyar should be excluded because each proffered expert reviewed and relied upon only a limited amount of available information in forming their opinions. Their decision to cherry-pick evidence renders their opinions unreliable.

1. Dr. Wylie's Opinions Should be Excluded Because She Failed to Employ an Appropriate Methodology

a. Dr. Wylie's Opinions Are Based on a Small Selection of Cherry-Picked Documents

Dr. Wylie only reviewed materials that were cherry-picked by J&J's lawyers. For example, she reviewed Dr. Fred Pooley's reports of his examination of samples taken from mines in Italy and Vermont and stated that they were necessary because "of the paucity of data in the literature."[66] Despite being asked "to find anything I could in the literature on the two mines in particular,"[67] she relied primarily on the

[66] Wylie Dep. at 58:18-24

[67] *Id.* at 84:8-10.

Pooley non-peer-reviewed reports "because [she] couldn't find much on the mine itself in Vermont."[68] However, Dr. Wylie was never informed that Dr. Pooley was deposed about his report as part of the J&J talcum powder product litigation.[69] She was also unaware that Dr. Pooley found asbestiform tremolite in Italian talc,[70] and that another Dr. Pooley report from 1977 found antigorite in samples from the Vermont talc mines.[71] She was not asked to review test results of any samples from the mines, only the "description of the geology of the mine."[72]

Dr. Wylie did not review any of J&J's internal testing documents.[73] She only asked for descriptions of the talc ore deposits, not for information regarding the J&J talcum powder product testing itself.[74] Dr. Wylie never saw core sampling results for the Argonaut mine in Vermont.[75] Dr. Wylie testified that the core sampling results—including results showing there was asbestos in the Argonaut mine—would not have been relevant to her opinions because she "had a very specific

[68] *Id.* at 84:12-14.

[69] *Id.* at 224:12-17.

[70] *Id.* at 226:11-16.

[71] *Id.* at 101:7-13.

[72] *Id.* at 59:7-9.

[73] *Id.* at 38:2-13.

[74] *Id.* at 39:15-17.

[75] *Id.* at 55:21-25.

assignment."[76] However, as discussed above, her "specific assignment" was to analyze and critique the work of Drs. Longo and Rigler, who *did test* the final J&J talcum powder products.[77] Even more puzzlingly, Dr. Wylie testified that she *would not have cared* if there were tests showing that asbestos was present at the mines used to source J&J talcum powder products, nor would she have cared if J&J failed to show her such tests.[78]

Dr. Wylie agrees that asbestos would not be present in the J&J end products unless asbestos was present at the mine or it was added at some later point for some reason.[79] Even though she was hired to critique Dr. Longo's and Dr. Rigler's findings, she never received or reviewed J&J's own internal test results to see if they supported or refuted Dr. Longo's and Dr. Rigler's conclusions.[80] Dr. Wylie did not speak to any J&J scientists.[81]

Other than Dr. Pooley's work, there is not a single citation in Dr. Wylie's report that is specific to the geology of the Vermont talc mines used to source J&J's

[76] *Id.* at 56:1-17.

[77] *Id.* at 56:7-17.

[78] *Id.* at 56:18-25.

[79] *Id.* at 229:9-16.

[80] *Id.* at 230:14-24.

[81] *Id.* at 39:22-24.

talcum powder.[82] And when she was asked about the limited data she did rely on, Dr. Wylie did not know what methodology was employed to gather that data.[83] Dr. Wylie relied solely on a public website as her source for information on mineral data at the Argonaut mine in Vermont, despite the fact that J&J had numerous analyses of the Argonaut and surrounding mines.[84] She also testified that she could not find much relevant information in the literature on China.[85] She had no idea when J&J used talc from the different mines in Vermont, Italy, and China, despite agreeing that "timing is relevant."[86] For example, she did not know that the Argonaut mine did not open until 1974.[87]

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[82] *Id.* at 50:14-21.

[83] *Id.* at 53:17-23.

[84] *Id.* at 54:11-55:2. *See also, e.g.*, JNJ000245002 (Colorado School of Mines Research Institute, Geology and Ore Reserves, Hammondsville Mine, 1970 (an analysis commissioned by J&J)), attached hereto as Exhibit K; IMERYS 219720 (Munro, RC, Cyprus Ore Reserves – Arsenic & Tremolite (1992)), attached hereto as Exhibit L; IMERYS 436972 (Gregg, WJ, Geology of Ore Reserves of the Hammondsville Ore Body (1978)), attached hereto as Exhibit M; IMERYS 425354 (R.C. Munro, Cyprus Ore Reserve Evaluation Preliminary Summary (describing the presence of fibrous tremolite and actinolite)), attached hereto as Exhibit N.

[85] *Id.* at 167:20-22. Though in J&J's possession, Dr. Wylie failed to consider a geological survey of the Chinese Longsheng talc mine where talc for Johnson's talcum powder products has been sourced since 2003: Li, Y. Y. (1979). Discussion on the genesis of Longsheng talc mine. Non-Metallic Mines, 1, 16-20, attached hereto as Exhibit O. This analysis, which was not shared with Dr. Wylie, evidences that talc within the mine was formed from tremolite.

[86] *Id.* at 51:17-52:15.

[87] *Id.* at 55:4-8.

Dr. Wylie differentiates between cosmetic and industrial talc, but was unaware that J&J used the same mines for both cosmetic and industrial talc—J&J did not give her that information.[88] She also acknowledged that she was, in fact, presented with many documents for the first time at her deposition that are relevant to whether there is asbestos in the J&J talcum powder products: "There certainly is a lot of information that you showed me."[89] Dr. Wylie did not conduct any independent research regarding the mines used to source J&J talcum powder products.[90] And while Dr. Wylie admits there is tremolite in the mines, she could not say how much because she was not asked to test the material—she said she would need to test it to be certain.[91]

b. Dr. Wylie's Opinions Rest on a Definition of Asbestos That is Not Supported by the Literature or Regulatory Standards

Dr. Wylie relies on a truly novel (and unsupported) definition of asbestos to support her opinion that asbestos is not present in the talc mines and, indeed, her definition differs from the definition set forth in J&J's own internal documents.[92] She takes the position that asbestos can only be conclusively identified when fiber

[88] *Id.* at 62:3-14; 64:9-65:15.

[89] *Id.* at 273:16-274:1.

[90] *Id.* at 54:25-55:2.

[91] *Id.* at 277:12-278:20.

[92] *Id.* at 108:5-20.

bundles are present,[93] and that asbestos requires a 20:1 mean aspect ratio—however, she cannot point to any support or source for that standard.[94] She disagrees with both the NIOSH and OSHA standards.[95] Dr. Wylie does not identify where in the geologic literature the standard used by her exists, if anywhere,[96] and she is unable to state how many fibers are needed to establish a population or bundle of fibers.[97] In contrast, Dr. Longo's and Dr. Rigler's reports discuss in detail the literature supporting an aspect ratio of 5:1 or greater and at least 0.5 µm in length, which is precisely what they identified in their testing of J&J talcum powder products.

Dr. Wylie also requires tensile strength in her definition of asbestos, despite conceding that *there is no way to test tensile strength and flexibility for a 5 micrometer particle*.[98] Further, she fails to define what "high tensile strength" would entail, or how flexible a fiber would need to be to qualify. NIOSH and OSHA standards do not require a finding regarding tensile strength.[99]

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[93] *Id.* at 149:16-23.

[94] *Id.* at 161:6-162:4.

[95] *Id.* at 109:8-20; 140:18-141:10.

[96] *Id.* at 183:21-184:8.

[97] *Id.* at 246:20-247:2.

[98] *Id.* at 206:12-17.

[99] *Id.* at 109:8-20; 140:18-141:10.

In sum, Dr. Wylie's opinions regarding the geology and the presence of asbestos in the mines sourced by J&J for its talcum powder product should be excluded. Dr. Wylie's opinions on this issue are based upon a limited amount of cherry-picked information and she fails to account for evidence that is contrary to her positions. Further, the opinions are not scientifically sound as they are based upon improper definitions and standards.

2. Dr. Dyar's Opinions Should be Excluded Because They Are Based Only on Subjective Belief and Unsupported Speculation

Dr. Dyar does not follow any scientific methodology and gives no expert opinions. There is no methodology in her report other than to criticize Drs. Longo and Rigler. Dr. Dyar acknowledges that her only objective was to "review the methodology used by Drs. Longo and Rigler in a series of reports and write a report giving my review."[100] To do this, she:

> first read the report carefully, every word. Then [] looked at all of the math and all the numbers and analyzed the numbers. Then [] sought out all of the references that were cited in those reports and tried to read all of them. And then [] looked at the report many times and tried to see if the information in the report justified the conclusions. (17:6-14).

Her report did not criticize the tools or standards Dr. Longo and his team used, rather she criticizes how his team followed the methods and applied judgment to

[100] Dyar Dep. at 16:15-22; 19:4-13.

interpreting the data. Dr. Dyar did this while acknowledging that she did not do any independent research for the report, other than teaching herself about topics she was unfamiliar with. She admitted that she had to look up every protocol that Dr. Longo followed[101] and teach herself about asbestiform bundles. In short, Dr. Dyar's opinions rely only upon her subjective belief and speculation.

Dr. Dyar did not test any Johnson's Baby Powder or Shower to Shower talcum powder to support the positions she has taken.[102] She did not ask to review the samples that Dr. Longo analyzed so that she could analyze them.[103] She did not test any talc ore or talcum powder that was mined in Vermont, Italy or China for the purposes of analyzing whether or not it contained asbestos or asbestos fibers.[104] She never reviewed any documents relating to anyone else's testing of the talc in J&J's mines or the finished product, other than Dr. Longo's and Rigler's.[105] Despite not checking the results herself, she did not think it was important to compare Dr. Longo's results and conclusions to what other scientists may have found when they analyzed the same materials or materials from the same places.[106]

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[101] *Id.* at 61:14-25; 62:22-63:21.

[102] *Id.* at 17:15-18.

[103] *Id.* at 23:3-12.

[104] *Id.* at 17:19-23.

[105] *Id. at* 77:1-23; 159:6- 160:10.

[106] *Id.* at 77:25 – 78:13.

a. Dr. Dyar's Criticism of Personnel and Methods are Based Upon Speculation

Dr. Dyar's criticisms are not founded in any sound methodology but, instead rely upon mere speculation. For example, Dr. Dyar criticizes Drs. Longo and Rigler for not properly training their personnel for possible impurities in talc samples where "the possible mineralogy is unconstrained." She claims that the analysts cannot "understand or interpret their results, especially where, as here, the impurities are tiny, and many possible minerals can be present."[107] However, Dr. Dyar acknowledges that she cannot say what the minerology is in talc or what possible minerals could actually be present.[108] Her report outlines minerals similar to talc in chemical formula but she cannot say that any of these minerals could feasibly be found in the samples provided by Johnson & Johnson or Imerys.[109] She claims there are hundreds of possibilities for misidentification but is unable to opine that any of the minerals subject to misidentification may actually be found in Vermont, China or Italy where J&J sourced for its talcum powder products.[110] She did not know, nor did she inquire, if the owners of the mines in Vermont analyzed and documented

[107] Dyar Report at 4.

[108] Dyar Dep. at 163:18-164:16.

[109] Dyar Report at 9.

[110] Dyar Dep. 163:18-164:16.

what material was being extracted from the mines over the course of the thirty-five years they were used to source J&J's talcum powder products.[111] Dr. Dyar's statements in this regard amount to nothing more than speculation and are not founded in science or accepted principles.

b. Dr. Dyar's Criticism of Definitions and Protocols Used by Dr. Longo Are Unsupported and Based Upon a Subjective Belief

Dr. Dyar criticizes Dr. Longo's definition of asbestos and focuses on the idea that asbestiform habit means the mineral can be separated into flexible fibers with high tensile strength.[112] Dr. Dyar repeatedly emphasizes the tensile strength and flexibility of the fibers to imply that these attributes can be tested to determine if a sample is asbestos. However, she could not identify any way to actually test for these attributes and admitted that she is "not familiar with the analytical techniques used to measure tensile strength or flexibility."[113] She admits that she did not even research the issue outside of determining the definition of asbestiform habit and has never tried to measure the tensile strength of asbestos.[114] Nor could she can't identify any literature documenting a methodology to test the tensile strength of a

[111] *Id.* at 164:18-166:19.

[112] Dyar Report at 10-13.

[113] Dyar Dep. at 341:1-7.

[114] *Id.* at 81:1-4.

fiber that is 10 microns or less.[115] She admitted she would have to do research to determine how to measure the flexibility of an asbestos fiber,[116] something that would have been reasonable to do prior to writing her report and opining on the the significance of flexibility. She initially testified that she could not recall if Yamate, ISO 22262-1 or 22262-2 sets forth any steps or methodologies to determine either the tensile strength or the flexibility of a fiber that is being analyzed, but later admitted she is not aware of any such steps in those testing protocols.[117] She has no opinion on whether there is any peer-reviewed publication that tells you how to measure tensile strength in an asbestos fiber or bundle which is 20 microns long or less and, once again, she didn't research that area.[118]

Dr. Dyar repeatedly criticizes Dr. Longo's team's interpretation of the EDS results.[119] However, she finds the protocols and methods that he uses to be robust.[120] Along the same lines, she claims that the EDS results in Dr. Longo's reports could be any number of minerals,[121] but her statements are unsupported by

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[115] *Id.* at 80:5-24.

[116] *Id.* at 85:15-86:14.

[117] *Id.* at 86:15-87:3; 336:3-19.

[118] *Id*. at 335:16-336:2.

[119] Dyar Report at 18-19.

[120] Dyar Dep. at 55:24-56:6; 106:12-20; 107;17-21.

[121] Dyar Report at 18-19.

references to published literature or governmental publications. Beyond that, she maintains this assertion despite not being able to opine that any of the other potential minerals have *ever* been identified in the mines from which J&J sourced talc.[122] More telling, Dr. Dyar admits that she could provide such an answer had she researched the issue, but she didn't.[123]

Dr. Dyar also is critical of Drs. Longo and Rigler for using the "eyeball" method of estimating EDS results, asserting that it is unsupported by the scientific community.[124] Dr. Dyar asserts that "it is important to do the calculations based on the peak areas with appropriate corrections in order to get even semi-quantitative data out of an EDS spectrum."[125] However, Dr. Dyar can point to no ISO or other standards that require quantitative data to analyze the chemical structure of a particle.[126] And, she has never tested an NIST reference sample of asbestos using EDS/EDXA to determine what the EDS spectra looks like for tremolite or anthophyllite.[127]

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[122] Dyar Dep. at 163:18-164:16

[123] *Id.* at 164:18-165:5.

[124] Dyar Report at 19.

[125] Dyar Dep. at 125:22-25.

[126] *Id.* at 126:1-129:14.

[127] *Id.* at124:4-13.

Dr. Dyar claims the Dr. Longo "deliberately avoided reporting the data that would actually be useful" when discussing quantitative data for EDS printouts.[128] However, Dr. Dyar never cites to a standard requiring the data formula print outs, and none of the testing methodologies used by Drs. Longo & Rigler (ISO 22262-1, ISO 22262-2 or Yamate) require that quantitative data be generated in order to analyze the chemical structure of a particle.[129] In fact, she cannot even point to a standard that requires a printout of the quantitative data similar to figure 7 of her report for purposes of analyzing the chemical structure of a mineral to determine whether it's consistent with asbestos.[130]

Dr. Dyar agrees that it's not necessary to print out the chemical composition if you already know what it is.[131] This principal would seem to apply when you have fewer choices and when asbestos is known to occur in the type of samples being reviewed. She notes that if you have "no idea and no independent constraints on what mineral it could be or what the composition could be" – it is your "obligation to produce as much quantitative information as possible."[132] However, she ignores the experience and knowledge of Dr. Longo and his team surrounding EDS

[128] Dyar Report at 23.

[129] Dyar Dep. at 126:1-131:10.

[130] *Id.* at 124:14-131:17; 137:2-139:9.

[131] *Id.* at 155:25-157:1.

[132] *Id.* at 156:21-157:1.

identification of asbestos materials. Dr. Longo's team was not looking for asbestos in an "unconstrained" environment. He was looking for asbestos in the context of the testing of historical samples where the mine or source of origin was known.[133]

Dr. Dyar also claims variability in results by date and analyst indicate incorrect findings and insists that because they were assigned at random the percentages of the minerals should be consistent and the geographical assignment was not biased.[134] However, she fails to take into account that the samples were not all received prior to when the testing began, so even though the samples were assigned randomly, Dr. Longo could only assign the samples that were in the lab's custody as of any given date. The results of the analysts could vary depending on the mine the samples came from given that the minerology of Vermont, China and Italy can differ; a fact that Dr. Dyar admits she knows nothing about.

Dr. Dyar was also ignorant of the percentage or ratio of tremolite and anthophyllite in the mines[135] so an analyst looking at mostly Vermont samples may

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[133] When confronted with numerous examples of EDS/EDXA analysis without quantitative data, including her own material, Dr. Dyar agreed that quantitative data was not always necessary. In fact, she acknowledged that it would not be appropriate to bring out the chemical analyses where the possible mineral was known based on independent studies. *See* Dyar Dep. at 158:5-8. Yet, the results of the Blount analysis of Vermont talc in her 1991 article (see Exhibit J, *infra*) are remarkably similar to Drs. Longo and Rigler's findings.

[134] Dyar Dep. at 245:7-253:19; Dyar Report at 24-27.

[135] *Id.* at 250-253; 255:10-256:1.

have different percentages of these materials than an analyst looking at samples from China. Dr. Dyar admitted that she was unaware of the mine locations for many samples.[136] Again, this is all information that was readily available for consideration had Dr. Dyar wanted to include it as part of her analysis.

c. Dr. Dyar's Criticism of Dr. Longo's Use of SAED are Purely Subjective

Dr. Dyar criticizes Dr. Longo's Selected Area Electron Diffraction technique (SAED). Specifically, she says that when employing SAED multiple zone axes are needed to identify asbestos.[137] Zone axis measurement "refers to the way the crystal was positioned at the time the x-ray pattern was collected relative to the crystal structure itself."[138] Dr. Dyar's opinion implies that multiple pictures must be present to prove that an analyst saw more than one two-dimensional view of a mineral. Dr. Dyar assumes that since there is only one image in Drs. Longo & Rigler's report their team could not have looked at it from two different angles as discussed in ISO 22262-1.[139] However, the lack of a photo does not mean the ISO process was not followed. Dr. Longo and Rigler's depositions indicated that analysts are tilting the goniometer and looking at the structure while examining it under the

[136] *Id.* at 255:20-23.

[137] Dyar Report at 28-32.

[138] Dyar Dep. at 200:6-16.

[139] *Id.* at 211:13-213:1.

electron microscope and making a determination in real-time as to whether or not the crystalline structure is consistent with asbestos. This practice meets the requirements of ISO-22262-1.

During her deposition, Dr. Dyar agreed that when looking at the substance or the structure through the TEM, the analyst "is rotating the material in real time and deciding when to make an image."[140] In fact, she acknowledged that it is standard operating procedure that an analyst "in reviewing the structure or substance in real-time, can decide to take an image of the selected area of diffraction pattern whenever, in his or her judgment, he finds something worth capturing."[141] Basically, the analyst can take a picture of the diffraction pattern at whatever points in time he or she thinks are important.[142] In contrast to her report, Dr. Dyar's testimony confirms that real-time review of the structure provides the multi-dimensional view.[143]

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[140] *Id.* at 40:13-19.

[141] *Id.* at 40:20 - 41:3; 41:24-42:4.

[142] *Id.* at 41:15-23.

[143] ISO 22262-1 describes looking at the sample with SAED in real-time and "if the results obtained from one ED pattern do not resolve any ambiguity in the identification of a fiber, a second ED pattern obtained at a different orientation of the fiber **can** be examined, and the observed tilt angle between the two orientations can be compared with the theoretical angle calculated from the suspected crystal structure." *See* Dyar Dep. at 206:4-210:23. ISO 22262-1 states "can" – not must or shall – when discussing a second view indicating that this is not a required step. *Id.* at 210:16-19.

Dr. Dyar complains that the report images are low quality and poorly documented. She also concludes that one can only identify asbestos from these images if they already concluded they were looking at asbestos prior to the SAED analysis.[144] She criticizes Dr. Longo but admits that this practice may be able to distinguish among species for materials that are already known to contain asbestos but would fail if the spectrum of possible mineralogy is broad.[145] Admittedly, she has no basis for saying the mineralogy in J&J's mines is broad. In light of the fact that Dr. Dyar could not even say whether there are three or more different minerals that could be identified in Vermont or Italian talc, she has no basis for saying that Dr. Longo's practice is unable to identify asbestos.[146]

Dr. Dyar also criticizes Dr. Longo for incomplete and unfeasible D spacing data.[147] "D spacing" is the distance between layers of atoms.[148] Dr. Dyar states that since the pixels are not clear – she can't recalculate their camera constant for each diffraction pattern and can't confirm the D spacings they list.[149] She maintains

[144] Dyar Report at 31.

[145] Dyar Dep. at 213:19-214:6; Dyar Report at 32.

[146] *Id.* at 220:21 – 221:14.

[147] Dyar Report at 33-41.

[148] Dyar Dep. at 200:6-16.

[149] *Id.* at 234:21-240:3.

her position, even though the camera constants were given, by refusing to admit that the "Camera K" is the number she is looking for.[150]

Dr. Dyar claims that more than 1000 minerals are in the D-spacing range listed in the report but, once again, she cannot say how many such minerals have been found in mines in Vermont used to source J&J talcum powder because she "does not know anything about the mineral assemblages present anywhere in Vermont."[151] She also criticizes two samples for unfeasible numbers despite there being over 180 samples.[152]

d. Dr. Dyar's Criticism of The Use of PLM is Based Upon Incomplete and Inaccurate Facts

Dr. Dyar agrees that "if done correctly [Polarized Light Microscopy] may" identify asbestos fibers,[153] noting that "PLM, when properly used, can identify asbestos mineral content by observing the morphology and refractive indices of the particles in the sample."[154] Dr. Dyar claims that the results among MAS analysts are inconsistent. However, she admits she did not take into account the time an analyst

[150] *Id.* at 239:9 -240:3.

[151] *Id.* at 240:24-241:11; Dyar Report at 35.

[152] *Id.* at 241:12-243:22.

[153] *Id.* at 213:19-214:6.

[154] Dyar Report at 43.

spent analyzing each sample, how much material was analyzed, or whether analysts were using an aberrational corrective lens.[155]

Dr. Dyar says that none of the PLM analyses show asbestos fibers or bundles and opines that all of the analyses are cleavage fragments.[156] Yet, she only researched what asbestos bundles actually look like in the course of writing her report. She admitted that she has "very little experience looking at amphibole bundles in thin section, which is why [she] referred to the literature to find what those images looked like."[157] Her lack of experience regarding asbestos bundles makes her unqualified to opine on this. She claims that she can tell the images contained cleavage fragments and not fibers based on her experience of examining minerals under a microscope and "I know what they look like"[158] despite having never attempted to identify asbestos fibers or bundles in a substance where she didn't know what it was.[159]

She also criticizes the images of dispersion staining contained in Dr. Longo's report, but incorrectly identifies an image as a dispersion staining image when it is

[155] Dyar Dep. at 272:21-278:7.

[156] *Id.* at 291:13-24.

[157] *Id.* at 293:21-294:17.

[158] *Id.* at 291:25-292:11.

[159] *Id.* at 297:15-19.

an elongation image.[160] Dr. Dyar condemns Dr. Longo for not using point counting, stating that it is the only way to estimate concentration by PLM,[161] but she cites to the wrong ISO standard and ignores its limitations.[162] The ISO protocol notes that it is not accurate if the sample is of different thicknesses or densities and she doesn't know if they were different thicknesses/densities or if the sample was sieved.[163]

e. Dr. Dyar is not Qualified to Opine on TEM and Her Opinions Pertaining to TEM Identification are Pure Conjecture

Dr. Dyar spends multiple pages critiquing Dr. Longo's TEM analysis,[164] yet she has almost no experience examining asbestos bundles under TEM and completely relies on the literature she has studied during the course of this litigation for her knowledge. She concedes the identification is highly subjective but has somehow become an expert in the several months she has been retained.

In her report, she notes that bundles occur with splayed ends.[165]However, when questioned, she cannot say whether that fiber bundles always exhibit splayed ends but agrees that ISO 22262-1 says that bundles may have splayed ends at either

[160] Dyar Report at 49; *see also* Dyar Dep. at 278:8-285:23.

[161] Dyar Report at 50-51.

[162] Dyar Dep. at 299:3-301:1.

[163] *Id.* at 303:24-307:25.

[164] *See* Dyar Report starting at 52.

[165] *Id.* at 53.

end of the bundle or not at all.[166] As noted above, she admits having "very little experience" with asbestos bundles.[167]

Dr. Dyar states that the only way to determine whether a population of amphiboles is asbestiform or not is based on statistical distinction between fibers and fragments.[168] However, when asked to explain the statistical calculation she is touting, she could not point to any generally accepted or relied upon standard which has a minimum number of fibers or structures necessary in order to analyze the aspect ratios. She could only say that you "need enough fibers to create distribution with an acceptable standard deviation on the mean."[169]

ISO 22262-1 states that "If any amphibole fibres longer than 5 microns with aspect ratios in the range of 20:1 or higher are observed, then it can be concluded that amphibole asbestos is probably present, with the degree of certainty increasing with increasing aspect ratio."[170] However, Dr. Dyar claims that it has to be an average aspect ratio in the range of 20 to 1 or higher, but cannot give a cite for this. She claims that average is implied despite terminology that says "any fibres."[171]

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[166] Dyar Dep. at 312:17- 315:5.

[167] *Id.* at 293:21-294:17.

[168] Dyar Report at 59.

[169] Dyar Dep. at 188:2-190:11.

[170] *Id.* at 319:12-320:18.

[171] *Id.* at 322:17-324:15.

Further, she says that populations must be used even though they are not outlined in the ISO protocol.[172] Dr. Dyar criticizes the population mean from Dr. Longo's report with an aspect ratio of 13.34 without being able to site to anything requiring a higher population mean.[173]

Dr. Dyar criticizes only counting particles with aspect ratios of greater than 5:1 and for not giving aspect ratios for studied particles.[174] However, she agrees that the report gives the data needed to calculate such aspect ratios.[175]

Dr. Dyar's opinions in regard to the work done by Drs. Longo and Rigler and their team of analysts should be excluded. Her opinions are founded on unsupported speculation and are without a sound scientific basis. Dr. Dyar's opinions and amount to nothing more than her a recitation of her subjective belief.

V. CONCLUSION

For this and the other foregoing reasons, the Court should exclude the opinions and testimony of Ann Wylie, Ph.D. related to the geology of the mines used to source J&J's talcum powder products, the presence of asbestos in the source mines and the talcum powder products, the definition of asbestos, the use of TEM testing

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[172] *Id.* at 318:16-319:4.

[173] Dyar Report at 65-66. *See also* Dyar Dep. at 328:24-329:22.

[174] Dyar Report at 65.

[175] Dyar Dep. at 326:21- 328:23.

generally, and the TEM testing of historical samples conducted by Drs. Longo and Rigler. In addition, the Court should exclude the opinions and testimony of Melinda Darby Dyer, Ph.D. in their entirety.

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